### REMARKS

The Advisory Action of November 9, 2009 denied entry of the two Declarations filed under 37 CFR 1.132, signed and dated October 14, 2009 and October 23, 2009, which accompanied the Request for Consideration of October 26, 2009.

This Amendment is being filed with a Request for Continued Examination, and, thus, consideration and entry of both the Request for Reconsideration filed October 26, 2009 and the present Amendment is respectfully requested.

## Status of the Claims

Claim 14 is amended. Support for the amendment may be found, for example on page 9 of the originally filed application.

Claim 15 is new, and is directed to the specific amount of octyl butyrate and glutamine peptides as supported by the original claims.

Claims 8-15 remain pending in this application.

# Claim Rejections-35 USC §112

Claims 11-14 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite.

The Request for Reconsideration filed October 26, 2009 responded to this rejection in a manner that successfully overcame the rejection according to the Advisory Action.

## Claim Rejections-35 USC §103

Claims 8-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over DESJONQUERES US 6,001,378 (DESJONQUERES) in view of HIRAMA et al. US 4,713,397 (HIRAMA) and ZAVERI et al. US 6,376,557(ZAVERI). This rejection is respectfully traversed.

The previously filed arguments in the Request for Reconsideration filed October 26, 2009 have been incorporated into the new arguments below.

DESJONQUERES discloses a composition for treating alopecia comprising an active principle containing: (i) peroxidized lipids and (ii) biologically active organosilicone derivatives. See, e.g., the abstract. Methylsilanol aspartate hydroxyprolinate is one of the seven organosilicon derivatives disclosed.

HIRAMA was offered for teaching benzyl nicotinate, as recited in the independent claims, for reducing hair fall out.

ZAVERI was offered for teaching an alopecia treatment using a commercially available mixture of octyl butyrate and glutamine-containing peptides.

The position of the Official Action was that it would have been obvious to combine the ingredients taught by these three documents to arrive at the claimed invention.

However, proposed combination fails to render obvious the claimed invention for the following three reasons:

## I. The combination fails to teach the claimed invention.

### A) Independent claims 8 and 11

These claims require a) octyl butyrate in an amount between 0.001 and 0.2% by weight, b) glutamine peptides in an amount between 0.001 and 0.2% by weight.

 $$\sf ZAVERI$$  requires a commercially available requires 0.5 to 4% of a mixture of octyl butyrate and glutamine-containing peptides.

There is no finding of fact concerning a) octyl butyrate in an amount between 0.001 and 0.2% by weight, b) glutamine peptides in an amount between 0.001 and 0.2% by weight.

Thus, as the combination solely specifies the amount of the composition comprising these two components, not the components individually, the combination fails to teach every feature of claims 8-13.

#### B) Independent claim 11

Claim 11 recites hydroxyproline and aspartic acid.

DESJONQUERES only discloses organosilicon derivatives.

Thus, there is no finding of fact as to hydroxyproline and aspartic acid, without the silanol complex, as recited in independent claim 11, having an effect on decreasing hair loss.

### C) Independent claim 14

Claim 14 is directed to a composition with active ingredients that consist of octyl butyrate, glutamine peptides,

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monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate.

All of the cited documents require <u>a combination</u> of actives in order to achieve a desired efficacy.

Thus, the combination fails to teach the composition defined by claims 14 and 15.

## II. There would have been no reason to approach claim 14.

Claim 14 is directed to a composition with active ingredients that <u>consist of</u> octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate.

DESJONQUERES requires peroxidzied lipids and organosilicon derivatives in order to achieve a synergistic effect (See, e.g., the Abstract and column 4, lines 43-53.)

Thus, one of ordinary skill in the art would have been strongly discouraged from approaching the composition of claim 14 (and dependent 15) as it would have required the removal of a necessary component from DESJONQUERES, which would have rendered the composition unsatisfactory for its intended use.

Indeed, the other cited documents require <u>a combination</u> of active ingredients in order to achieve a desired efficacy. HIRAMA requires ubiquinone with optional ingredients (e.g., the abstract), and ZAVERI discloses "ingredients essential for accomplishing the desired results" in addition to the mixture of

octyl butyrate and glutamine-containing peptides (e.g., column 4, lines 11-30).

Thus, one of ordinary skill in the art would have been strongly discouraged from merely picking and choosing one or more actives from each of these compositions, as the single actives themselves are not disclosed as providing the desired results.

# III. The combination fails to recognize the superior results.

The combination fails to (i) disclose a preference for monomethylsilanol-hydroxyproline aspartate, as recited in independent claim 8, (ii) suggest the use of the combination of hydroxyproline and aspartic acid themselves, as recited in independent claims 11, and (iii) suggest only the use of the active ingredients as recited in claim 14, in a composition for combating or delaying hair loss. Additionally, there is no suggestion of the superior results obtained by the claimed invention.

DESJONQUERES requires peroxidzied lipids and organosilicon derivatives in order to achieve a synergistic effect (See, e.g., the Abstract and column 4, lines 43-53.) Monomethylsilanol-hydroxyproline aspartate (as recited in independent claims 8 and 11) is neither claimed nor exemplified as a preferred component.

HIRAMA is directed ubiquinone-containing drugs which may be combined with a skin peripheral vasodilator drug such as

carpronium chloride, vitamin E nicotinate, or benzyl nicotinate. See, e.g., the Abstract and column 1, lines 10-30.

ZAVERI discloses "ingredients essential for accomplishing the desired results" in addition to the commercial mixture of octyl butyrate and glutamine-containing peptides(e.g., column 4, lines 11-30). In one embodiment the amount is 0.5 to 4%, and in another embodiment 2.45% (See, e.g., tables 1 and 4 and column 4, lines 11-15). However, ZAVERI requires the composition as a whole for efficacy.

In the declaration signed and dated October 14, 2009, the results illustrate that the efficacy of the composition according to independent claims 8 and 14 (e.g., active ingredients octyl butyrate glutamine peptides, monomethylsilanol-hydroxyproline aspartate and benzyl nicotinate with panthenol) is superior to a composition of octyl butyrate and glutamine alone. For example, the claimed invention reduces hair loss in one third the time in half as many applications as that of a composition of octyl butyrate and glutamine alone. See, e.g., the table on p. 7.

The declaration signed and dated October 23, 2009 explains the properties of the individual components, and that the aim of the claimed invention is to interfere with various mechanisms of hair loss without exerting any local pharmacological or systemic action.

With respect to independent claim 11, as evidenced by the discussion in the specification (e.g., page 4, lines 20-29

and page 5, lines 8-19 and 25-35) and the declaration signed and dated October 23, 2009, the combination of hydroxyproline and aspartic acid contribute to the anti-hair loss activity, which the proposed combination fails to suggest.

Therefore, as the proposed combination fails to teach or suggest the claimed invention and the unexpected superior results of the claims 8-15, withdrawal of the rejection is respectfully requested.

## Conclusion

In view of the amendment to the claims, the previously filed declarations and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

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The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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